

JAN.19.2004 2:55PM LEGAL DEPARTMENT

NO.185 P.2/3

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/027,669
Applicants : Rama Akella and John P. Ranieri
Filed : December 21, 2001
For : Povidone-Containing Carriers for Polypeptide Growth Factors

Confirmation No. 1708

TC/A.U. : 1654
Examiner : Jeffrey B. Russel

OFFICIAL

Atty. Dkt. No.: SBI-111
Date: January 19, 2004

DECLARATION OF RICHARD J. MAY

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PURPOSE OF DECLARATION

1. This Declaration is submitted in conjunction with a Response to the Office Action dated November 19, 2003, and is for the purpose of aiding in overcoming one or more ground of rejection or requirement made in that Office Action. This Declaration is to establish that Sulzer Carbomedics Inc. and Sulzer Biologics Inc. (formerly Sulzer Orthopedics Biologics Inc.) were commonly owned during the time relevant to the above-identified application.

STATEMENT OF FACTS

2. I, Richard J. May, am presently employed by Centerpulse USA Inc., at Houston, Texas as Group Vice President Finance & Tax Counsel. I was Treasurer of Sulzer Biologics Inc. (formerly Sulzer Orthopedics Biologics Inc.) of Austin, Texas and Treasurer of Sulzer Carbomedics Inc. of Austin, Texas.

3. I have knowledge of the ownership status of Sulzer Biologics Inc. (formerly Sulzer Orthopedics Biologics Inc.) and Sulzer Carbomedics Inc. throughout the period of time beginning at least as early as 1996 and continuing until at least January 2003.

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4. Attached to this Declaration is a redacted copy of the Confidentiality Agreement dated July 17, 1998 between Sulzer Carbomedics Inc. and Professor Dr. L. K. von Segesser, showing at least the date of execution, the subject of the agreement, the publication clause, and the signatures of the parties.

5. At the time the Confidentiality Agreement was executed by the parties on July 17, 1998, Sulzer Biologics Inc. (the original assignee of the above-identified patent application) was known as Sulzer Orthopedics Biologics Inc. and was owned by Sulzer Orthopedics Inc., which was owned by Sulzer Medica USA Holding Co. At the same time, Sulzer Carbomedics Inc. was also owned by Sulzer Medica USA Holding Co. Sulzer Carbomedics Inc., as signatory to the attached Confidentiality Agreement, acted on behalf of Sulzer Biologics Inc. (formerly Sulzer Orthopedics Biologics Inc.).

DECLARATION

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Full name: Richard J. May

Date: January 19, 2004

Signature: Richard J. May

Attachment: (redacted) Confidentiality Agreement dated July 17, 1998

117520.01 / 1596-01700

Page 2 of 2

CONFIDENTIALITY AGREEMENT

This Agreement made as of 7 17. 1998, 1998, by and between Sulzer Carbomedics Inc. ("Sulzer Carbomedics") a Delaware corporation with a place of business at 1300 East Anderson Lane, Austin, Texas 78717 and Prof. Dr. L.K. von Segesser ("Prof. von Segesser"), Chef de Service de Chirurgie, Service de chirurgie cardio-vasculaire CHUV, CH-1011 Lausanne, Switzerland.

Sulzer Carbomedics and Prof. von Segesser desire to enter into preliminary discussions concerning testing of Sulzer Carbomedics' angiogenic growth factor in a porcine ischemia/TMLR model ("Project").

In the course of such discussions it will be necessary for each party to disclose to the other certain information which such party deems to be confidential ("Confidential Information")

To protect such Confidential Information, the parties (the party disclosing the Confidential Information and the party receiving same being referred to hereinafter as "Discloser" and "Recipient", respectively) agree as follows:

1.

2.

SEGESSER.MUT/CONFID

- 1 -

9. Prof. von Segesser may publish investigative results regarding the Project only in accordance with the procedure set forth herein. Such publication may include presentation of Project material (including heretofore Confidential Information) by written means, oral means or other means of public disclosure. Two weeks prior to any proposed publication, Prof. von Segesser will provide copies of the applicable publication manuscript to Sulzer Carbomedics for review. Prof. von Segesser may proceed with publication if, within two weeks of Sulzer Carbomedics' receipt of the publication manuscript, Sulzer Carbomedics does not object to Prof. von Segesser publication. In the event that Sulzer Carbomedics objects to Prof. von Segesser publication within two weeks of manuscript submission, Prof. von Segesser will not publish or otherwise disclose to any third party any of the information contained in the manuscript and such manuscript shall become Confidential Information subject to the terms of this Agreement.

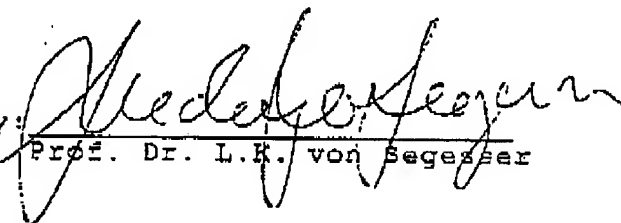
Each party acknowledges its acceptance of this Agreement by the signature below of its authorized officer on duplicate counterparts of the Agreement, one of which fully executed counterpart is to be retained by each party.

SULZER CARBOMEDICS INC.

By:  7-13-08

Printed Name: Charles D. Griffin

Title: Vice President/General Manager

By: 
Prof. Dr. L.R. von Segesser

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SULZER BIOLOGICS

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/027,669 Confirmation No. 1708
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TC/A.U. : 1654
Examiner : Jeffrey E. Russel

Atty. Dkt. No.: SBI-111
Date: January 19, 2004

DECLARATION OF DR. RAMA AKELLA

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

PURPOSE OF DECLARATION

1. This Declaration is to establish the deficiency of at least the following technical journal article as prior art against the above-identified U.S. patent application:

Xavier M. Mueller et al. *Swiss. Med. Wkly.* 131:23-25 (2001)

STATEMENT OF FACTS

2. I, Dr. Rama Akella, am a named inventor in the above-identified patent application. I have read the specification and claims in the above-identified pending patent application and am familiar with the invention described therein. I have also read the Mueller et al. reference noted above and understand its teachings.

3. At the request of the owner and the inventors of the instant application, and upon execution of a Confidentiality Agreement between Sulzer Carbomedics Inc. and Professor Dr. L. K. von Segesser on July 17, 1998,

(a) the present invention was disclosed to Professor von Segesser and his associates,

(b) a sample of the bone-derived growth factor composition (described in the present application and referred to in the Mueller et al. article) was provided to Professor von Segesser, and

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SULZER BIOLOGICS

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(c) a series of studies of the bone-derived growth factor composition, including povidone-containing compositions, was commissioned by the inventors and Sulzer Carbomedics, Inc. to be performed by Professor von Segesser and his associates.

The study protocols were then finalized by the parties, and the studies were conducted in the laboratories of Professor Segesser. Dr. Xavier M. Mueller, the first named author of the above-cited reference, was at that time a surgeon working under the direction of Professor Segesser at the Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland. The cited publication, in which Professor von Segesser is a named author, is a report of the results of some portion of those studies.

4. A redacted copy of the above-mentioned Confidentiality Agreement is attached showing the date of execution, the subject of the agreement, the publication clause, and the signatures of the parties.

5. The present inventors had possession of the claimed invention prior to the publication date of the Mueller et al. reference.

TIME OF PRESENTATION OF THE DECLARATION

6. This Declaration is submitted with the Response to the Office Action dated November 19, 2003, and is for the purpose of overcoming one or more ground of rejection or requirement made in that Office Action.

DECLARATION

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Full name: Rama Akella, Ph.D

Date: January 19, 2004

Signature: Akella Rama

Attachment: (redacted) Confidentiality Agreement dated July 17, 1998

117520.01 / 1536-01700

Page 2 of 2

CONFIDENTIALITY AGREEMENT

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Sulzer Carbomedics and Prof. von Segesser desire to enter into preliminary discussions concerning testing of Sulzer Carbomedics' angiogenic growth factor in a porcine ischemia/TMLR model ("Project").

In the course of such discussions it will be necessary for each party to disclose to the other certain information which such party deems to be confidential ("Confidential Information")

To protect such Confidential Information, the parties (the party disclosing the Confidential Information and the party receiving same being referred to hereinafter as "Discloser" and "Recipient", respectively) agree as follows:

1.

2.

SEGESSER, MUT/CONFID

- 1 -

9. Prof. von Segesser may publish investigative results regarding the Project only in accordance with the procedure set forth herein. Such publication may include presentation of Project material (including heretofore Confidential Information) by written means, oral means or other means of public disclosure.

Two weeks prior to any proposed publication, Prof. von Segesser will provide copies of the applicable publication manuscript to Sulzer Carbomedics for review. Prof. von Segesser may proceed with publication if, within two weeks of Sulzer Carbomedics' receipt of the publication manuscript, Sulzer Carbomedics does not object to Prof. von Segesser publication. In the event that Sulzer Carbomedics objects to Prof. von Segesser publication within two weeks of manuscript submission, Prof. von Segesser will not publish or otherwise disclose to any third party any of the information contained in the manuscript and such manuscript shall become Confidential Information subject to the terms of this Agreement.

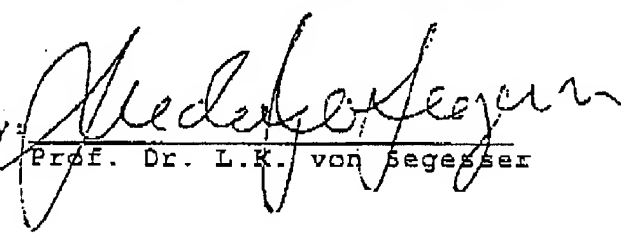
Each party acknowledges its acceptance of this Agreement by the signature below of its authorized officer on duplicate counterparts of the Agreement, one of which fully executed counterpart is to be retained by each party.

SULZER CARBOMEDICS INC.

By:  7-13-04

Printed Name: Charles D. Griffin

Title: Vice President | General Manager

By: 
Prof. Dr. L.K. von Segesser